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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/611,398	06/30/2003	Mariagrazia Pizza	PP00338.105	1890

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 09/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/611,398	PIZZA ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 10-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-4, 10-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4 and 10-25 are pending.

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claim1-4, 15-25, drawn to a plurality of immunogenic detoxified species of protein, classified in class 530, subclass 350.

   II. Claims 10-11, drawn to methods of vaccinating to prevent or treat a disease in a subject, classified in class 424, subclass 261.1.

   III. Claims 12-14, drawn to methods of formulating a vaccine, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions Group I and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product can be utilized in methods of screening for antibodies directed to the immunogenic protein (affinity purification of antibodies or in detection methods), in methods of making molecular image polymers and in methods of screening for modulating products that evidence protease activity as the claimed immunogenic protein could be used as a substrate.

3. Inventions Groups I and Group III are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as

claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case that the process as claimed can be used to make another and materially different product, wherein pharmaceutically acceptable carriers are know to be used in diagnostic methods in association with detection reagents, such as the immunogenic detoxified protein, and therefore the process could be used to formulate detection kit reagents, or a diagnostic composition.

4. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

5. This application contains claims directed to the following patentably distinct species: Group I contains 6 patentably distinct species:

6. species 1, Cholera toxin subunit A, with a mutation through substitution of Asn or Gly (claims 15-18 and 23)

7. species 2, Cholera toxin subunit A fragment with corresponding mutations and substitution of Asn or Gly(claims 15-18 and 23);

8. species 3, Escherichia coli heat labile toxin subunit A with a mutation through substitution of Asn or Gly.(claims 19-23)

9. species 4, Cholera toxin A subunit with Cholera toxin subunit B (claims 4 and 23-24)

10. species 5, Cholera toxin A fragment with Cholera toxin subunit B (claims 4 and 23-24)

11. species 6, Escherichia coli heat labile toxin subunit A and subunit B (claims 4, and 25) The species are independent or distinct because the claimed immunogenic detoxified proteins differ in structure, biological function and resultant biological effects, such as the antibodies stimulated or detected would differ based upon the overall size and sequence of the immunogenic detoxified proteins.

12. Group II, 6 patentably distinct methods of vaccinating.

13. species 1, Cholera toxin subunit A, with a mutation through substitution of Asn or Gly (claims 15-18 and 23)

14. species 2, Cholera toxin subunit A fragment with corresponding mutations and substitution of Asn or Gly(claims 15-18 and 23);

15. species 3, Escherichia coli heat labile toxin subunit A with a mutation through substitution of Asn or Gly.(claims 19-23)

16. species 4, Cholera toxin A subunit with Cholera toxin subunit B (claims 4 and 23-24)

17. species 5, Cholera toxin A fragment with Cholera toxin subunit B (claims 4 and 23-24)

18. species 6, Escherichia coli heat labile toxin subunit A and subunit B (claims 4, and 25) The species are independent or distinct because the claimed immunogenic detoxified proteins differ in structure, biological function and resultant biological effects, such as the antibodies stimulated or detected would differ based upon the overall size and sequence of the immunogenic detoxified proteins.

19. Group III contains 6 patentably distinct species of method of formulating:

20. species 1, Cholera toxin subunit A, with a mutation through substitution of Asn or Gly (claims 15-18 and 23)

21. species 2, Cholera toxin subunit A fragment with corresponding mutations and substitution of Asn or Gly(claims 15-18 and 23);

22. species 3, Escherichia coli heat labile toxin subunit A with a mutation through substitution of Asn or Gly.(claims 19-23)

23. species 4, Cholera toxin A subunit with Cholera toxin subunit B (claims 4 and 23-24)

24. species 5, Cholera toxin A fragment with Cholera toxin subunit B (claims 4 and 23-24)

species 6, Escherichia coli heat labile toxin subunit A and subunit B (claims 4, and 25)

The species are independent or distinct because the claimed immunogenic detoxified proteins differ in structure, biological function and resultant biological effects, such as the antibodies stimulated or detected would differ based upon the overall size and sequence of the immunogenic detoxified proteins. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-3 and 23 generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

25. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

26. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on flextime, but usually M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, A. Mark Navarro can be reached on (571) 272-0861. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Vgp
September 15, 2006

MARK NAVARRO
PRIMARY EXAMINER